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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,003	12/13/2006	Surender Kharbanda	GENU:005US/10605111	1914

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EXAMINER	
GUSSOW, ANNE	
ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
05/13/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

aopatent@fulbright.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,003	KHARBANDA ET AL.	
	Examiner	Art Unit	
	ANNE GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-15* is/are pending in the application.

4a) Of the above claim(s) *10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 6 has been amended.

Claim 3 has been previously cancelled.

Claims 10-14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 16, 2009.

2. Claims 1, 2, 4-9, and 15 are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The rejection of claims 1, 2, 4-9, and 15 under 35 U.S.C. 103(a) as being obvious over Wreschner (a) (US PG PUB 2005/0019324) or Hoogenboom, et al. (WO 2003/089451) in view of Capon, et al. (US PAT 5,116,964) and Wreschner (b) (WO 96/03502) is maintained.

Applicant's arguments filed March 7, 2011 have been carefully considered by the examiner but they are deemed not to be persuasive. The response states that reading Capon, there is no discussion to indicate that adding an Fc molecule to a ligand would have any practical benefit for producing antibodies. In fact, it is well accepted that producing antibodies can be achieved, in most cases, simply by repeated administration of significant quantities of antigen. Clearly, as the examiner has shown, MUC1-EC was a well known antigen and could have been produced and administered for the purpose of antibody production without the need to engage in the complicated engineering called for by Capon.

Turning to the MUC1 references, Wreschner A discusses for the most part the use of ligands to MUC1-EC. This is reflected throughout the specification, and where it does discuss administering MUC1-EC, it is solely for the purpose of producing antibodies. As such, the combination of Capon with Wreschner A simply does not make sense. Wreschner B has a similar, though more subtle inconsistency with Capon. While there is discussion of administering the compositions of Wreschner B to a subject for therapy, the only claim directed to that subject matter, claim 14, carefully excludes subject matter where the MUC 1 receptor lacks tandem repeats. This distinguishing language is also found at page 12 of the application in the second full paragraph. Thus, while tandem repeat deletions might have been suitable as pharmaceutical agents for the production of antibodies, as in Wreschner A, they were clearly not intended for use as therapeutics per se. (see response pages 4-6).

Response to Arguments

In response to these arguments, the claims are drawn to a chimeric protein comprising a first polypeptide sequence that is a MUC1-EC polypeptide and a second sequence which is a human immunoglobulin Fc or a human albumin polypeptide. The MUC1-EC sequences as claimed were known in the art in both Wreschner (a) and Hoogenboom (see sequence alignments mailed October 5, 2010). Applicant's arguments regarding the production of antibodies appears misplaced in view of the claims, since the claims are not drawn to an antibody, the claims are drawn to a fusion protein. However, these arguments will be addressed here – The examiner agrees that Capon is not using fusion proteins to produce antibodies. Capon teach the production of hybrid immunoglobulin molecules comprising an Fc region and a ligand binding domain. It is well known in the art to create fusion proteins, particularly with Fc regions. The key here is that the molecules of Capon are HYBRID molecules, thus not from a naturally occurring antibody molecule. One of ordinary skill in the art would be able to create any number of hybrid immunoglobulin molecules specifically since Capon teaches "A large number of proteinaceous substances are known to function by binding specifically to target molecules. These target molecules are generally, but need not be, proteins. The substances which bind to target molecules or ligands are referred to herein as ligand binding partners, and include receptors and carrier proteins, as well as hormones cellular adhesive proteins, tissue-specific adhesion factors, lectin binding molecules growth factors, enzymes, nutrient substances and the like." (see column 2 specifically) Thus, any of a number of ligands, including the MUC1-EC as taught by Wreschner (a) can be fused to an Fc region in view of the teachings of Capon. The use

of the MUC1-EC by Wreschner (a) to produce an antibody is not relevant to the molecule of Capon.

Regarding the Kharbanda declaration, the examiner has reviewed the data presented regarding the instantly claimed fusion molecule. The data provide production of a fusion protein comprising the MUC1-EC and Fc. The data indicate that these molecules inhibit breast cancer cell proliferation and lung cancer cell proliferation. These results are not surprising since Wreschner (b) teaches that a number of isoforms of MUC1 are expressed on breast cancer cells and that administration of soluble MUC1 isoforms inhibited the growth of breast cancer cells (see figures 3-6 of Wreschner (b)). Thus, it was known in the art that administration of MUC1 proteins could inhibit the proliferation of breast cancer cells.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
May 4, 2011

/Anne M. Gussow/
Primary Examiner, Art Unit 1643